

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated May 12, 2006 (hereinafter Office Action) have been considered. Claims 1-15 and 24-54 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Applicant respectfully traverses each of the Section 103(a) rejections, each of which relies at least in part on a combination of U.S. Patent No. 6,638,268 to Niazi (hereinafter “Niazi”) in view of U.S. Patent No. 4,586,923 to Gould *et al.* (hereinafter “Gould”) and U.S. Patent No. 6,408,214 to Williams *et al.* (hereinafter “Williams”) because a skilled artisan would not have been motivated to combine these references as asserted by the Examiner. In order to maintain a §103(a) rejection, the Examiner must provide evidence from the cited references of motivation to combine the references as asserted. *See, e.g.*, MPEP §2143. Each of the relied-upon references fails to teach limitations of the claimed invention that would prevent a skilled artisan from looking to the cited references to create a combination that allegedly corresponds to the claimed invention. The proffered motivations for the asserted combinations are discussed below.

In the effort to re-create Applicant’s claimed invention, the Examiner primarily relies upon the teachings of Niazi, which admittedly fails to teach aspects of the claimed invention. The Examiner acknowledges that Niazi at least fails to teach a steering mechanism comprising a lever and an inner sheath assuming a pre-formed shape that is different from the shape of an outer sheath when the distal end of the inner sheath is extended beyond the distal end of the outer sheath. Niazi also fails to teach an inner sheath that is axially rotatable relative to the outer sheath. As can be seen by Figure 1 of Niazi, both the inner and outer catheters together are referred to as catheter 10, the outer catheter is denoted as outer catheter 11, and the inner catheter is denoted inner catheter 12. When describing rotation, Niazi refers to rotation of both inner and outer catheters together and does not teach axial rotation of the inner catheter with respect to the outer catheter. *See, e.g.*, column 4, line 30: “Catheter 10 is rotated until tip 17 lies within the tricuspid valve.” The cited portion at column 3 of Niazi merely describes “an inner catheter 12, which slides

in and out of outer catheter 11.” However, there is no discussion of axial rotation of one catheter with respect to the other catheter. Due to at least these deficiencies in the teachings of Niazi, the Examiner proposes modifying Niazi’s teachings with the teachings of Gould and Williams.

The Examiner relies upon the teachings of Gould to replace the “torque screw as disclosed by Niazi with a pivotably connected lever as taught by Gould” because Gould allegedly teaches that a torque screw and lever are functionally equivalent and therefore interchangeable. However, this proffered motivation is illogical as it directly indicates that a skilled artisan would not be motivated modify Niazi as asserted. If a lever and torque screw were functionally equivalent and interchangeable as asserted by the Examiner, a skilled artisan would not have been motivated to change one to the other because there would be no reason to do so. Given the Examiner’s reasoning, Niazi’s torque screw already performs the same functions that the asserted lever would; therefore, there is no motivation to change the torque screw to a lever. Moreover, no evidence has been presented to indicate that any such motivation exists. Without the requisite presentation of evidence of motivation, the §103(a) rejection is improper and should not be maintained.

Applicant further disagrees with the Examiner’s assertion that a torque screw and lever are functionally equivalent and therefore interchangeable in the context of the present invention. For example, and as argued previously, Applicant’s pivotably disposed steering mechanism lever facilitates single-hand manipulation of the steering mechanism, whereas the rotatable torque screw mechanism of Niazi and the other asserted references require two-hand manipulation (one hand to rotate the torque screw and the other hand placed on the outer sheath). In the context of the presently claimed subject matter, the Examiner’s assertion of functional equivalency and interchangeability with regard to a torque screw and lever is erroneous and without basis. The Examiner has merely cited a reference that teaches different embodiments using different mechanisms in the context of that specific reference. Because no evidence has been provided to show that a torque screw and lever are functionally equivalent or interchangeable apart from the context of Gould, it would appear that the Examiner is impermissibly taking official notice of this assertion as constituting a

fact outside of the record which is capable of instant and unquestionable demonstration as being well known or obvious to one skilled in the art. Applicant respectfully disagrees and requests that the Examiner produce a reference that supports the Examiner's assertion that a torque screw and lever are functionally equivalent or interchangeable.

Moreover, a skilled artisan would not have looked to Gould to modify Niazi because Gould does not teach an open lumen, telescopic inner and outer catheters, or a pre-formed shape of a flexible end. Gould does not contemplate the catheter of Niazi and would not be consulted in an attempt to modify Niazi. This piecemeal selection of elements is tantamount to mixing teachings out of context. Such a rejection is not permissible under §103. *See In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000) (proposed modification must not be made in the abstract but rather made in view of the entire teaching of the prior art).

The Examiner also relies upon the teachings of Williams to "modify the inner sheath as disclosed by Niazi to assume a pre-formed shape different from the shape of the outer sheath" to "allow for a substantial number of two and three-dimensional curvatures to assist in navigating a catheter through a patient's vasculature." As the Examiner notes, Williams teaches using a pre-formed shape of an inner sheath to navigate a catheter through a patient's heart. *See, e.g.*, column 4, lines 61-64. However, Williams does this because Williams does not teach a steering mechanism. In contrast, Niazi teaches a steering mechanism (cited by the Examiner as torque screw 29) and would therefore, not require further structure to assist in navigating a catheter through a patient's heart. A skilled artisan would not be motivated to introduce unnecessary navigation structure to Niazi when Niazi already teaches a manner of navigating a catheter. Without the requisite presentation of evidence of motivation, the §103(a) rejection is improper and should not be maintained.

Moreover, reliance upon Williams to overcome Niazi's failure to teach an inner sheath that is axially rotatable relative to an outer sheath would not satisfy the requisite motivation for a §103(a) rejection. As discussed above, Niazi fails to contemplate a need for inner and outer sheath rotation relative to one another at least because the dual catheter assembly 10 may be rotated. For at least these reasons and those discussed above, no evidence of motivation to combine the teachings of Niazi and Williams can be found in the

references themselves. It is a requirement that actual evidence of a suggestion, teaching or motivation to combine prior art references be shown, and that this evidence be "clear and particular." *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999). Broad conclusory statements regarding the teaching of references, standing alone, are not evidence. *Id.* Niazi and Williams fail to provide clear and particularized teaching, suggestion or motivation to combine their teachings in the manner suggested by the Examiner. Without the requisite presentation of evidence of motivation, the §103(a) rejection is improper and should not be maintained.

As the above-discussed combination is asserted against each of the independent claims, Applicant submits that each of the independent claims is allowable over the asserted combination for at least the lack of a compelling presentation of evidence of motivation to combine the references as asserted. Applicant accordingly requests that the §103(a) rejections be withdrawn.

Each of the dependent claims depends from independent Claim 1 or 24. Each of the rejections of the dependent claims relies on the above-discussed proposed combination of Niazi, Gould and Williams along with another reference added to the combination to meet additional limitations of the rejected dependent claims. Applicant asserts that the arguments made above with respect to the failure of the asserted combination to provide the requisite teaching, suggestion or motivation to combine reference teachings relative to Applicant's independent claims 1 and 24 also apply to the combinations asserted against the dependent claims as the additionally cited references fail to overcome the above-discussed impropriety of the base combination of Niazi, Gould and Williams.

While Applicant does not acquiesce to any particular rejections of these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 24. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious."

M.P.E.P. §2143.03; *citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent Claims 2-15 and 23-24 are also allowable over the asserted combinations of references.

With particular respect to the rejection of dependent Claims 9, 10, 38 and 39, Applicant further traverses because the asserted combination of references does not teach or suggest each of the claimed limitations. The Examiner acknowledges that the asserted combination of Niazi, Gould, and Williams does not teach at least one pressure sensing device connected to the inner or outer sheath and relies upon the teaching of U.S. Patent No. 6,533,770 to Lepulu *et al.* (hereinafter "Lepulu"). Applicant notes that each of above-listed dependent claims includes limitations directed to a pressure sensing device connected to the distal end of an inner or outer sheath. The cited portion of Lepulu instead teaches a pressure sensor 362 connected to the proximal end of cannula 354. Lepulu does not teach the claimed pressure sensing device connected to the distal end of an inner or outer sheath. Without a presentation of correspondence to each of the claimed limitations, the §103(a) rejection of dependent Claims 9, 10, 38 and 39 is improper, and Applicant accordingly requests that it be withdrawn.

With particular respect to the rejection of dependent Claims 43-45 and 49-51 based upon the above-discussed combination in further combination with the teachings of U.S. Patent No. 5,462,527 to Stevens-Wright *et al.* (hereinafter "Stevens"), Applicant respectfully traverses because the asserted combination of references does not teach or suggest each of the claimed limitations. The Examiner acknowledges that the asserted combination of Niazi, Gould, and Williams does not teach at least a steering handle including a retention mechanism configured to retain the steering handle at a fixed position. In an attempt to overcome this deficiency, the Examiner cites a portion of Stevens which teaches a retention method for a thumb wheel steering mechanism. Applicant notes that the claimed steering mechanism comprises a lever and the claimed retention mechanism is configured to retain the steering handle of a lever at a fixed position. Stevens does not teach any sort of steering mechanism involving a lever and therefore, does not teach a retention mechanism configured to retain the steering handle of a lever. Without a

presentation of correspondence to each of the claimed limitations, the §103(a) rejection of dependent Claims 9, 10, 38 and 39 is improper, and Applicant accordingly requests that it be withdrawn.

It is to be understood that Applicant does not acquiesce to Examiner's characterization of the asserted art or Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicant's claimed subject matter. Moreover, Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of Applicant's invention, officially noticed facts, and the like. Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching, suggestion or motivation to combine reference teachings. Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.038US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact her at the number below to discuss any issues related to this case.

Respectfully submitted,

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